LATOURETTE) that the House suspend the rules and pass the bill, H.R. 2672.

The question was taken; and (two-thirds having voted in favor thereof) the rules were suspended and the bill was passed.

A motion to reconsider was laid on the table.

GENERAL LEAVE

Mr. LATOURETTE. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks and include extraneous materials on H.R. 5427, H.R. 5335, H.R. 5083, and H.R. 2672, the matters just considered by the House.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Ohio?

There was no objection.

PERMISSION FOR COMMITTEE ON ENERGY AND COMMERCE TO FILE SUPPLEMENTAL REPORT ON H.R. 3580

Mr. BURR of North Carolina. Mr. Speaker, I ask unanimous consent that the Committee on Energy and Commerce be allowed to file a supplemental report on H.R. 3580.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Ohio?

There was no objection.

MEDICAL DEVICE USER FEE AND MODERNIZATION ACT OF 2002

Mr. BURR of North Carolina. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 3580) to amend the Federal Food, Drug, and Cosmetic Act to make improvements in the regulation of medical devices, and for other purposes.

The Clerk read as follows:

H.R. 3580

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Medical Device User Fee and Modernization Act of 2002''.

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

TITLE I—FEES RELATED TO MEDICAL DEVICES

SEC. 101. FINDINGS.

The Congress finds that—

(1) prompt approval and clearance of safe and effective devices is critical to the improvement of the public health so that patients may enjoy the benefits of devices to diagnose, treat, and prevent disease;

(2) the public health will be served by furnishing additional funds for the review of devices so that statutorily mandated deadlines may be met; and

(3) the fees authorized by the amendment made by section 102 will be dedicated to meeting the goals identified in the letters from the Secretary of Health and Human Services to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate.

SEC. 102. ESTABLISHMENT OF PROGRAM.

(a) IN GENERAL.—Subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379F et seq.) is amended by adding at the end the following part:

''PART 3—FEES RELATING TO DEVICES

''SEC. 737. DEFINITIONS.

''For purposes of this subchapter:

''(1) The term 'premarket application' means—

''(A) an application for approval of a device submitted under section 515(c) or section 351 of the Public Health Service Act; or

''(B) a product development protocol described in section 515(f).

Such term does not include a supplement, a premarket report, or a premarket notification submission.

''(2) The term 'premarket report' means a report submitted under section 510(o)(3).

''(3) The term 'premarket notification submission' means a report submitted under section 510(k).

''(4)(A) The term 'supplement', with respect to a panel-track supplement, a 180-day supplement, a real-time supplement, or an efficacy supplement, means a request to the Secretary to approve a change in a device for which—

''(i) an application has been approved under section 515(d) or under section 351 of the Public Health Service Act; or

''(ii) a notice of completion has become effective under section 515(f).

''(B) The term 'panel-track supplement' means a supplement to an approved premarket application under section 515 that requests a significant change in design or performance of the device, or a new indication for use of the device, and for which clinical data are generally necessary to provide a reasonable assurance of safety and effectiveness.

''(C) The term '180-day supplement' means a supplement to an approved premarket application under section 515 that is not a panel-track supplement and requests a significant change in components, materials, design, specification, software, color additives, or labeling.

''(D) The term 'real-time supplement' means a supplement to an approved premarket application under section 515 that requests a minor change to the device, such as a minor change to the design of the device, software, manufacturing, sterilization, or labeling, and for which the applicant has requested and the agency has granted a meeting or similar forum to jointly review and determine the status of the supplement.

''(E) The term 'efficacy supplement' means a supplement to an approved premarket application under section 351 of the Public Health Service Act that requires substantive clinical data.

''(5) The term 'process for the review of device applications' means the following activities of the Secretary with respect to the review of premarket applications, premarket reports, supplements, and premarket notification submissions:

''(A) The activities necessary for the review of premarket applications, premarket reports, supplements, and premarket notification submissions.

''(B) The issuance of action letters that allow the marketing of devices or which set forth in detail the specific deficiencies in such applications, reports, supplements, or submissions and, where appropriate, the actions necessary to place them in condition for approval.

''(C) The inspection of manufacturing establishments and other facilities undertaken as part of the Secretary's review of pending premarket applications, premarket reports, and supplements.

''(D) Monitoring of research conducted in connection with the review of such applications, reports, supplements, and submissions.

''(E) Review of device applications subject to section 351 of the Public Health Service Act for an investigational new drug application under section 505(i) or for an investigational device exemption under section 520(g) and activities conducted in anticipation of the submission of such applications under section 505(i) or 520(g).

''(F) The development of guidance, policy documents, or regulations to improve the process for the review of premarket applications, premarket reports, supplements, and premarket notification submissions.

''(G) The development of voluntary test methods, consensus standards, or mandatory performance standards under section 514 in connection with the review of such applications, reports, supplements, or submissions and related activities.

''(H) The provision of technical assistance to device manufacturers in connection with the submission of such applications, reports, supplements, or submissions.

''(I) Any activity undertaken under section 513 or 515(i) in connection with the initial classification or reclassification of a device or under section 515(b) in connection with any requirement for approval of a device.

''(J) Evaluation of postmarket studies required as a condition of an approval of a premarket application under section 515 or section 351 of the Public Health Service Act.

''(K) Compiling, developing, and reviewing information on relevant devices to identify safety and effectiveness issues for devices subject to premarket applications, premarket reports, supplements, or premarket notification submissions.

''(6) The term 'costs of resources allocated for the process for the review of device applications' means the expenses incurred in connection with the process for the review of device applications for—

''(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers, employees, and committees and to contracts with such contractors;